JUN 7 - 2005

510k SUMMARY
OF SAFETY AND EFFECTIVENESS

K 051103

Date of Summary: 23 May 2005

Submitter's Name:

Haag-Streit USA Inc.
5500 Courseview Drive
Mason, Ohio 45040-2398

Contact Person:

Eduardo March
Senior Consultant
AAC Consulting Group Inc.
7361 Calhoun Place, Suite 500
Rockville, MD 20855

Phone- 301.838.3120
Fax: 301.838.3182

Name of Devices:

Haag-Streit Contact Glasses

Classification Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
Product Code: HJK
Regulatory Class: II

DEVICE DESCRIPTION

The HS Contact Glasses is a family of diagnostic and therapeutic contact lenses used for eye examination and therapy of intraocular abnormalities.

The HS Contact Glass family is designed around the classic Goldmann contact lenses. All HS Contact Glass models are of similar design, but provide different optical elements to provide excellent visualization of the ocular anatomical areas for the particular intended use. When used in conjunction with the HS 900 slit-lamp, the HS Contact Glasses provide a binocular and stereoscopic view of the specific optical region of the eye.

The HS Contact Glass typically consists of an aluminum housing, one or more mirror elements and a curved shell of plastic (acrylic) or mineral glass that is applied for a short period of time directly on the globe or cornea of the eye.

The HS contact glass family has two principal modes of use. Those lenses used for diagnostic and others used with laser radiation for therapy of ocular abnormalities.

HS Contact Glasses used in diagnostic procedures are made of acrylic plastic (PMMA). These are designed for the examination of the entire fundus, the vitreous and the irido-corneal angle with slit-lamps, such as the Haag-Streit 900 model. Many of HS diagnostic Contact Glasses have the original mirror angle by Goldmann: 59/ 66/ 73 degrees.

Intended Uses:

The Haag-Streit Contact Glasses are a family of diagnostic / therapeutic contact lenses used in the examination of eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

Substantial Equivalence:

The diagnostic and laser therapy HS Contact Glass are equivalent to other lenses described in Part 886.185. The agency has previously cleared diagnostic and laser therapy use contact lenses constructed of PMMA and mineral glass. The HS Contact Glasses are substantially equivalent to diagnostic and laser therapy use lenses marketed by Volk Optical Inc. (Quadraspheric Fundus Lens- K943125 and K023221) and Ocular Instruments Inc. (Saurenghi Scan Laser Lens- K014170).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Haag-Streit USA, Inc.
c/o Eduardo March
Senior Consultant
AAC Consulting Group, Inc.
7361 Calhoun Place, Suite 500
Rockville, MD 20855

Re: K051103
Trade/Device Name: Haag-Streit Contact Glasses
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
Regulatory Class: Class II
Product Code: HJK
Dated: April 29, 2005
Received: May 4, 2005

Dear Mr. March:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) NUMBER (If known): K051103

Device Name:

Haag-Streit Contact Glasses

Indications for Use:

The Haag-Streit Contact Glasses are a family of diagnostic and therapeutic contact lenses use in the examination of the eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

(Please do not write below this line – Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use _____
(Per 21 CFR 801.109)

Daniel W. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051103